

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,588	12/20/2001	Frederic Andre	SANSYL002	1696
5487	7590 04/06/2006		EXAMINER	
ROSS J. OEHLER			FUBARA, BLESSING M	
AVENTIS PHARMACEUTICALS INC. 1041 ROUTE 202-206			ART UNIT	PAPER NUMBER
MAIL CODE: D303A			1618	
BRIDGEWATER, NJ 08807			DATE MAILED: 04/06/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/019,588	ANDRE ET AL.			
Office Action Summary	Examiner	Art Unit			
	Blessing M. Fubara	1618			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time 17 rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	J. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on 03 Ja	1) Responsive to communication(s) filed on <u>03 January 2006</u> .				
2a) This action is FINAL . 2b) ☐ This	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
 4) Claim(s) 1,3,4,6-9,11-23,25-33 and 35 is/are per 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1,3,4,7-9,11-23,25-33 and 35 is/are ref 7) Claim(s) 6 is/are objected to. 8) Claim(s) are subject to restriction and/or 	vn from consideration.				
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)		(DTO 440)			
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/3/06. 	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa				

DETAILED ACTION

Examiner acknowledges receipt request for continued examination filed under 37 CFR 1.114, request for extension of time, IDS, amendment and remarks, all filed 1/03/06. Claims 1, 3, 4, 6-9, 11-23, 25-33 and 35 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 1/3/06 has been entered.

Claim Rejections - 35 USC § 103

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 1, 3, 4, 7-9, 11-23, 25-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talton (US 6,406,745).

Talton discloses composition comprising coated core comprising particles, phosphatidylcholine zwitterion, morphine, EUDRAGIT, HPMC (abstract, column 12, lines 12-22; column 20, line 13; columns 21 and 22; Examples 3, 4 and 9). The difference between the instant claims and the prior art is the amount of the zwitterionic surfactant in relation to the EUDRAGIT polymer. Regarding the size of the particles, there is no demonstration that the

Art Unit: 1618

recited sizes provide unusual/unexpected results. And generally, differences in amounts of the surfactant will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the dosage of Talton. One having ordinary skill in the art would do so and to use amounts of the surfactant relative to the methacrylate copolymer, an amount that would be expected to produce dosage form having the desired release profile.

4. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose cocamidopropylbetaine zwitterionic surfactant.

CLAIM 19: this claim does not have the proper status identifier, claim 35 is a new claim and thus claim 19 should have been currently amended.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Application/Control Number: 10/019,588

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Page 4

Blessing Fubara Abbusant Patent Examiner

Tech. Center 1600